

C2 32 (amended). The process of claim 25 wherein the calcium lactate solution is made in a fermentation process.

Remarks

Claims 29, 30 and 32 have been amended to depend from claim 25 rather than claim 24. These amendments provide antecedent basis for "calcium lactate solution" in those claims.

The following remarks address the 35 USC §103(a) rejections stated in the previous final office action.

Claims 1, 13, 21 and 24-39 stand rejected under 35 USC §103(a) over the combination of Bailey et al. and Lehnhardt et al. This rejection is traversed.

As to claims 1 and 24-37:

All of these claims require a concentration step, or specify some range of lactic acid in the acidulated solution that is subjected to extraction. In claim 24, for example, the claimed process comprises extracting an acidulated solution containing 12-60% lactic acid with an amine extractant to form a loaded solvent, and removing lactic acid from the loaded solvent.

Claims 1, 25-27, 29-30, 32, 33 and 36, 37 and 39 further define the acidulated solution as being formed by acidulating a calcium lactate solution.

Bailey describes a process whereby an amine extractant is used to remove lactic acid from an acidulated lactic acid solution. As discussed in the previous response, Bailey only describes using dilute acidulated lactic acid solutions in the extraction process. This is shown in his Examples 4-8, where the highest lactic acid concentration shown is just above 4%. Nothing in the Bailey suggests anything at all concerning using more concentrated lactic acid solutions in the extraction process.

Concentrating a lactic acid solution from the 4% range of Bailey to the 12% minimum required by claim 24 is by no means trivial. It would require removing nearly 2/3 of the total volume from Bailey's acidulated solution. This would require a significant

investment in equipment, energy or both to achieve. One would not undertake this step unless there were a clear reason to do so.

Lehnhardt describes a process in which lactic acid is extracted from an acidulated solution using an oxygenated solvent. Lehnhardt's process uses a highly concentrated acidulated lactic acid solution (38-65%, per column 5 lines 58-59) as a starting material for the extraction. Unlike the process of the present claims, Lehnhardt's process does not involve an amine extractant.

The examiner's position is since that Lehnhardt describes extractions from highly concentrated lactic acid solutions, it would have been obvious to modify Bailey by starting with a more concentrated lactic acid solution. The examiner views Lehnhardt as describing "the same basic steps as Bailey—fermentation, acidulation, extraction" (office action page 4).

The examiner's argument ignores the fact that Bailey's extraction is altogether different from Lehnhardt's.

Lehnhardt's extraction is characterized by two features, neither of which is present in Bailey's (or that of the present invention). First, the acidulated starting solution must be saturated in certain electrolytes. *See, e.g.*, column 2 lines 16-24, column 3 lines 34-42, column 6 lines 10-15, among many other places. Second, the extraction is done using an extractant that includes, and preferably consists essentially of, water, a mineral acid and an oxygenated organic solvent. *See* column 6 lines 30-34.

Lehnhardt's extraction works because the electrolyte in effect "salts out" the lactic acid, making it less soluble in the aqueous phase, thereby increasing the driving force that causes the lactic acid to migrate into the organic phase. *See* column 4 lines 6-12. This is to be contrasted with the mechanism by which Bailey's extraction operates. In Bailey's extraction, it is the pH gradient between the acidulated solution and the amine extractant that drives the lactic acid to migrate from the starting solution into the extractant. Column 10 lines 53-57.

So, the references that the examiner would combine to establish a *prima facie* case of obviousness each describe significantly different extraction processes, which work in different ways. There is nothing in either reference to suggest that operating conditions that are suitable for one of these processes would be suitable for the other.

Once one understands the mechanism by which Lehnhardt's process works, the reason he requires a highly concentrated starting solution becomes apparent and it

becomes equally apparent that this reason is not applicable to Bailey's process. As shown, Lehnhardt requires his starting solution to be *substantially saturated* with an electrolyte. He forms this electrolyte during the acidulation process, by causing the added acid to react with the lactic acid salt (specified as a sodium, ammonium or potassium salt), forming free lactic acid and the electrolyte. See column 5 lines 31-34 and column 6 lines 4-15. Because the acidulated solution must be *substantially saturated* with electrolyte, it is necessary to start with a concentrated lactic acid solution in order to end up with the requisitely concentrated solution. Without the concentration step, the acidulated solution will not be substantially saturated as required.

Bailey's process does not require an acidulated solution that is saturated with electrolytes, because his extraction process is driven by pH variances, not a salting out effect. One of ordinary skill in the art would not, on the basis of Lehnhardt, see any advantage in concentrating the starting solutions used in Bailey's process. The reasons Lehnhardt uses concentrated starting solutions simply do not exist in Bailey's process. Note that the minimum concentration of claims 24-31 is fully three times the maximum described by Bailey. Absent the clear suggestion of some benefit, one of ordinary skill can hardly be expected to incur the substantial costs of concentrating Bailey's starting solutions.

Further, there is no basis to expect, on the basis of Lehnhardt, that any improvements would be seen in Bailey's process by increasing the lactic acid concentration of the acidulated solution. Notwithstanding the examiner's interpretation of figure 4 of this application, the data there clearly shows that once the lactic acid concentration in the acidulated solution reaches 12% or more, the concentration of lactic acid that is transferred to the organic phase does increase dramatically. This increase is much more than an extrapolation of the data points below 12% lactic acid concentration would suggest. Even if the references created a *prima facie* case of patentability, this data is clear evidence of unexpected results that support the unobviousness of the invention as claimed.

Claims 1, 25-27, 29-30, 32, 33 and 36, 37 and 39 require the acidulated solution to be made by acidulating a calcium lactate solution with sulfuric acid. Neither reference describes this step. It is expressly excluded from Lehnhardt's process, as requires the lactic acid to be in the sodium, potassium or ammonium form in order to produce the electrolyte in the acidulation step. And, contrary to the examiner's assertions, Bailey does not describe this step either. At column 6, Bailey describes adding "salts of calcium, magnesium,

potassium and phosphate" to the fermentation medium, but does not identify what those salts might be or how much might be used. At column 7, top, Bailey describes an illustrative media that includes a very small quantity of calcium chloride. Calcium chloride is a substantially neutral salt that would not be expected to neutralize lactic acid to form calcium lactate. Calcium lactate formation requires the addition of basic calcium compounds such as calcium hydroxide or calcium carbonate, as described on page 16, lines 3-5 of the specification.

Accordingly, claims 1, 25-27, 29-30, 32, 33 and 36, 37 and 39 are patentable over the references for this additional reason.

As to claims 28, 38 and 39:

These claims require that the amine extractant contain sulfuric acid. This feature is not described in either reference, and so claims 28, 38 and 39 are allowable on this basis. It is acknowledged that Lehnhardt describes including an organic acid in his extractant, but that extractant does not include an amine. Due to the different methods by which Bailey's and Lehnhardt's extraction processes operate, there is no reason for one skilled in the art to add an acid into Bailey's different extraction media on the basis of Lehnhardt's teaching.

Conclusion

As the examiner has acknowledged, neither reference alone discloses the process now claimed. Although the references both described extraction processes for removing lactic acid from an acidulated solution, the processes are different from one another, and operate in different ways. For this reason, one of ordinary skill in the art would not select process parameters useful in the Lehnhardt process and apply them to the Bailey process, absent some clear suggestion that some advantage would be gained in that way. Neither reference provides any reason to modify the Bailey process to increase the starting concentration of lactic acid 3-fold or more, or to add an acid to Bailey's extraction media. The process as claimed is therefore patentable over the combination of Bailey and Lehnhardt.

A notice of allowance is respectfully requested.

Respectfully submitted,
GARY C. COHN PLLC

Gary C. Cohn
Registration No. 30,456
Phone: (425) 576-1656
4010 Lake Washington Blvd. NE
Suite 105
Kirkland, WA 98033

Appendix—Version with Markings to Show Changes Made:

Additions are indicated by underlining, deletions by brackets ().

Claim 31 has been canceled.

Claims 29, 30 and 32 have been amended as follows:

29 (amended). The process of claim [24] 25 wherein the pH of the calcium lactate solution prior to acidulation is between about 5.0 and about 9.0.

30 (amended). The process of claim [24] 25 wherein the pH of the calcium lactate solution prior to acidulation is less than 5.0.

32 (amended). The process of claim [24] 25 wherein the calcium lactate solution is made in a fermentation process.